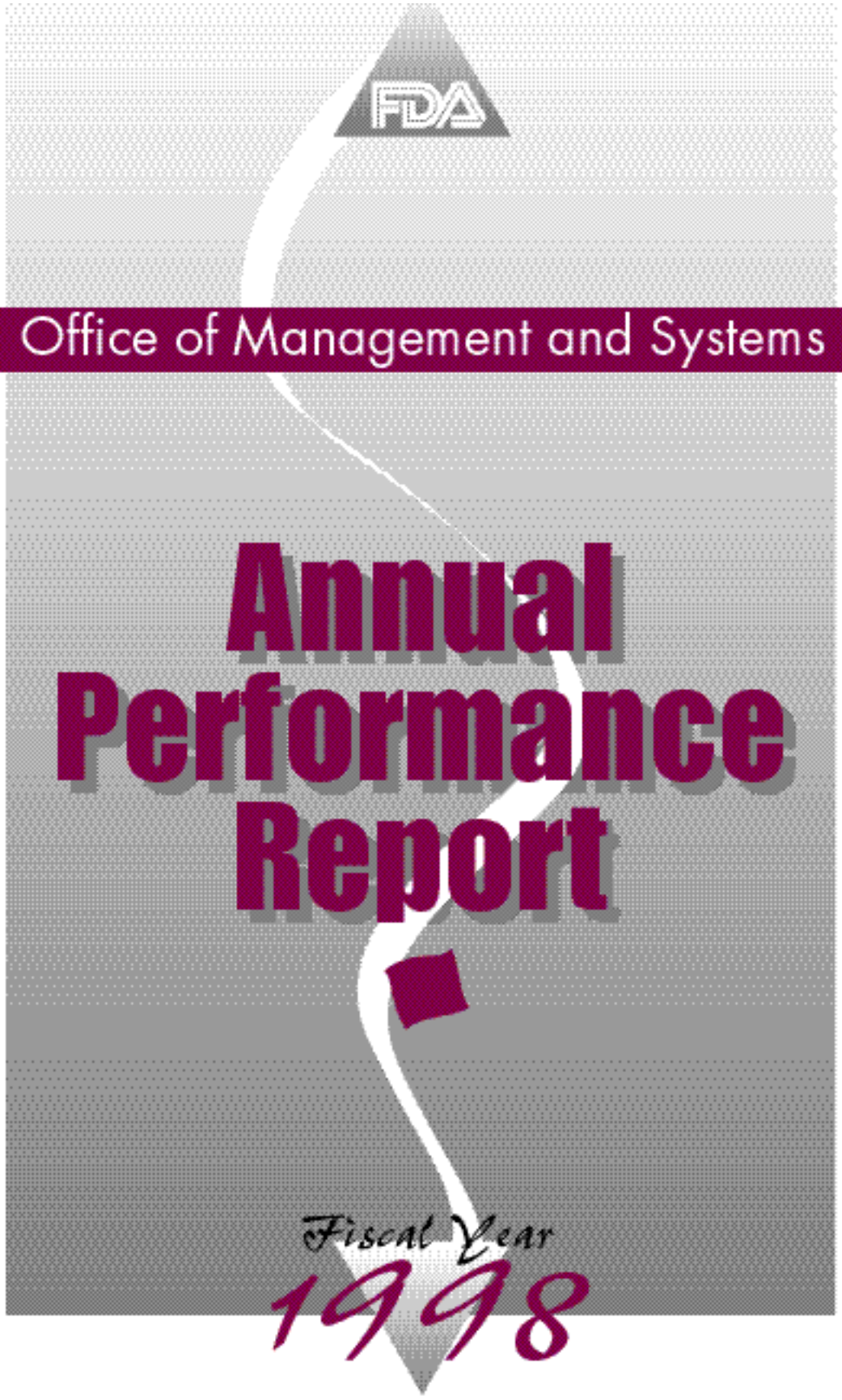

Office of Management and Systems

Annual Performance Report

Fiscal Year 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES Food and Drug Administration

Rockville MD 20857

December 1, 1998

Dear Colleague:

I am pleased to share with you the Food and Drug Administration (FDA), Office of Management and Systems' (OMS') third annual performance report. This report highlights OMS/Agency accomplishments during fiscal year 1998 and is intended to let our customers and partners know what we have done and are doing to help support the Agency's public health mission.

Fiscal year 1998 was very busy and productive for the OMS team. The accomplishments of the OMS team, however, are reflective of the cooperation and commitment of senior management and the collective efforts of the entire FDA workforce. I would like to thank my colleagues within OMS, the Agency, and the Department for their assistance. I especially thank the Agency's Executive Officers and their staffs for their essential contribution to the Agency's corporate success.

Our activities over the last year reflected a continued emphasis on strategic management, quality investments in information technology (with special emphasis on Year 2000 strategy), performance improvement through better communications, streamlining business processes, incorporating change, and improving the quality of work life throughout the Agency. We have assisted managers throughout FDA as they focused on the integration of new, innovative approaches to managing scarce Agency resources.

In fiscal year 1999, OMS and the Agency must address even greater challenges as we manage under very tight fiscal constraints and in compliance with the requirements of the FDA Modernization Act. Because of these constraints and requirements, the Agency must further increase its effort to rework the way it does business in order to carry out its public health mission.

It remains a privilege to work with the many talented and dedicated individuals who have contributed to our accomplishments. I look forward to working together over the next year as we discover new opportunities in response to the challenges which lie ahead. If you have any questions or comments about this report, you can reach me on (301) 827-3443 or at my e-mail address: rbyrd@bangate.fda.gov.

Sincerely,

Robert J Byrd

Robert J. Byrd
Deputy Commissioner
for Management and Systems,
Chief Financial Officer

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Executive Summary

Last year, OMS identified several priority initiatives for FY 1998 and beyond, including:

- achieving a five percent reduction in central account expenditures
- streamlining budget execution reporting
- expanding electronic access to FDA's regulatory documents
- forming partnership agreements with Centers for sharing facility responsibilities
- leading Agency efforts to develop and implement performance-based management
- expanding the Information Technology (IT) Business Planning Review Process
- implementing the Electronic Gateway to support electronic submissions of adverse events reporting
- completing the Enterprise Administrative Support Environment (EASE) pilot and implementing the automated Time and Attendance module

As a result of Agencywide cooperation and the efforts of the entire FDA management team, we were able to achieve all of our FY 1998 goals in these areas, and we are pleased to share our major accomplishments with you in this report. In addition to the items above, OMS played a leading role in helping the Agency to plan and manage both the Prescription Drug User Fee Act (PDUFA) reauthorization budget and the FDA Modernization Act (FDAMA) implementation.

Throughout FY 1998, OMS components also worked to improve and re-develop internal business processes. Initiatives undertaken during this year included:

- facilitating Agencywide engagement and ownership in formulating the FY 2000 FDA budget request in a strategic context
- performing a complete assessment of the telecommunications operation and budget
- improving communication with internal and external customers by expanding use of Internet and Intranet
- initiating Agencywide investment in, and implementation of, the Information Systems Architecture (ISA) program to eliminate barriers in exchanging regulatory documents and to facilitate the seamless exchange of information

- establishing an Agencywide Human Resources Council to provide a forum for sharing information on human resources issues and best practices
- leading Agency efforts to ensure Year 2000 compliance of FDA's entire information technology architecture including systems and infrastructure
- undertaking a comprehensive plan of action to correct noted deficiencies in the Agency's property management and accounting systems
- initiating new payroll management strategies which focused management attention on payroll cost control at the Center and Office level
- conducting Stakeholder Engagement Forums in accordance with FDAMA, Section 406(b), in order to hear from our stakeholders on how FDA might best meet the requirements of the FDA Modernization Act
- satisfying FDAMA, Section 407, by developing a report that documents the status and costs associated with establishing an information system to track applications or submissions requesting Agency action

In FY 1999 and beyond, OMS must address additional challenges, particularly in financial and strategic resource management. In this regard, OMS will continue the cost-saving and cost-avoidance initiatives already underway, and will initiate further improvements including:

- ensuring that FDAMA planning and reporting requirements are met in a timely and complete manner and that the 406(b) plan is incorporated in the strategic management of the Agency
- ensuring that all FDA mission critical systems are verified as Y2K compliant by December 31, 1998 and all other systems are compliant by March 31, 1999
- partnering with the National Treasury Employees Union (NTEU) in order to resolve workplace issues of mutual concern to management and the Union in a cooperative manner
- continuing work with FDA components, the General Services Administration (GSA) and the Office of Management and Budget (OMB) on the financial strategy for the consolidation of FDA at White Oak, Maryland
- working toward completing the construction of the FDA College Park Building to consolidate the headquarters components of the Center for Food Safety and Applied Nutrition (CFSAN) and to house the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), a partnership with CFSAN, the Center for Veterinary Medicine (CVM) and the University of Maryland, College Park

- continuing construction of the Arkansas Regional Laboratory and the New York Laboratory, and the design of the Los Angeles (Irvine) Laboratory as part of the Agency's strategic plan to reduce facility costs by consolidating FDA field laboratories across the nation

- implementing more effective payroll management in Center and Office components

- deploying and fully implementing the Information Systems Architecture (ISA) by FY 2000 to eliminate Agencywide barriers to information exchange

Program Summary

•• Who We Are ••

The Office of Management and Systems is the business arm of the Food and Drug Administration. OMS consists of five major components concentrating on the cost efficient and effective management of "people, money, things, planning, and systems." We are an organization of 583 employees, serving the Agency's 8,999 employees nationwide. The OMS team, as we are referred to, includes the Office of the Deputy Commissioner and his immediate staff, including the Associate Commissioner for Strategic Management; the Office of Human Resources and Management Services; the Office of Financial Management; the Office of Facilities, Acquisitions, and Central Services; the Office of Planning and Evaluation; and the Office of Information Resources Management. We are an integral part of the top FDA management team and provide leadership, guidance, and solutions to a wide and varied number of management and resource issues facing the FDA. We are a customer-focused organization, supporting the management of the Agency's resources in a collaborative, coordinated, and cost effective fashion.

•• What We Do ••

PEOPLE: We provide a full range of human resource management services to FDA employees. Most employees work in the greater Washington, D.C. area, but almost 3,000 scientists, technicians, and staff are located in field offices from Maine to Hawaii and Puerto Rico to Alaska. Our quality personnel services include staffing, recruitment, position classification, compensation, training, awards, performance management, employee relations, labor relations, and ethics. We also conduct management and organizational studies, administer FDA's Delegations of Authority program, oversee FDA's Advisory Committee and Internal Controls programs, and provide public access to FDA's regulatory dockets.

MONEY: We provide resource management leadership and a full range of professional financial services throughout FDA. OMS serves as the focal point for Agencywide financial management including budget planning, preparation, formulation, execution and control; accounting, payment processing, financial reporting, foreign and

domestic travel management, employee relocation, and payroll liaison; and financial systems development, maintenance, coordination, and integration. We monitor and track an annual total budget exceeding $1 billion, which includes two direct appropriations and four separate and unique user fee activities. We pay more than 90,000 invoices per year, and process vendor payments of more than $198 million, with more than $143 million made via wire transfer. We develop, operate, maintain, and continuously update FDA's central financial systems. We manage FDA's annual budget hearings with DHHS, OMB, and the House and Senate Appropriations Subcommittees.

THINGS: We provide an efficient and effective program of nationwide logistical support for FDA in the areas of real and personal property, purchasing, grants, physical security, engineering services, environmental, safety, health, and long range planning for the Agency's future facilities. This involves significant resources including annual lease costs of $85.7 million, and owned facilities valued at $147.3 million.* We manage 230 government owned or leased buildings and facilities nationwide, totaling 4.3 million square feet. In addition, we manage 42,000 line items of personal property with an acquisition cost of $198.6 million. In FY 1998, the contracting program totaled $186.9 million in contracts, $33.2 million in small purchases, $18.7 million in International Merchant Purchase Authorization Card (IMPAC) transactions, and $21.6 million in grants/cooperative agreements.

* - Includes NCTR (several buildings counted as one facility). OFACS manages and operates these facilities via a number of service contracts.

PLANS & EVALUATIONS: We develop and implement an Agencywide platform for strategic and budgetary decision making through the use of systematic processes for developing consensus and establishing priorities among FDA senior managers. We develop short-term program plans and long range strategic plans required by a range of reform and performance acts and ensure that reporting requirements are met. We conduct program and policy studies to assist management in efficiently allocating resources, improving program and project performance, and evaluating the impact of Agency activities. We prepare economic analyses to support management decisions on Agency policy issues, and to provide a foundation for most Agency rulemaking and proposed legislation.

SYSTEMS: We coordinate information technology and business life-cycle manage-

ment activities such as strategic business planning that begins with creating a vision and developing goals, strategies, and plans to move the enterprise into the future. We are responsible for building and maintaining an information technology infrastructure, directing future IT investments, providing leadership for the Agency's Year 2000 compliance mandates, and insuring interoperability of the FDA systems. In addition, we provide information technology services to support programmatic and administrative operations. Such services include telecommunications support, Intranet and Internet management, systems development [e.g., Administrative Systems Automation Project] information collection, information dissemination, records and forms management, IT policy development, as well as information technology security. Within the context of these IT activities, we operate the process by which strategic IT investment decisions are made on approximately $18 million of major IT Agency initiatives and an additional $30 million for the PDUFA II information management program. FDA's total annual obligations for information technology are approximately $125 million.

STRATEGIC MANAGEMENT: We develop, implement, and coordinate Agencywide efforts to manage strategically. This includes the development of the FDAMA 406(b) plan and its subsequent reports to Congress. In addition, we manage a twice yearly Strategic Management Forum that focuses senior level Agency managers on the important issues of priority setting and resource allocation. These activities set Agency direction for the short term as well as long term in relationship to program direction and management focus.

•• Why We Do It ••

By providing cost-effective resource management and efficient central services, OMS helps all FDA components save money and staff. Because of the tight fiscal constraints under which the Agency operates, we continue to encourage or direct the investment of Agency resources in areas which will return the greatest benefit in supporting the Agency's public health mission. Our goal for the next four years ending FY 2002, during which the Agency is expected to be impacted by the balanced budget agreement, is to provide strategic guidance on how FDA can best defend and support its budget requests; to oversee the strategic management of Agency resources and business practices; and to continue to reduce the cost of Agency support services. We strive to accomplish this while maintaining our customer focus and improving program oversight and internal business processes.

Major Accomplishments in FY 1998

During FY 1998, OMS continued to focus its efforts on improving strategic management, internal business processes, and overall Agency operations. We did so by: (1) promoting sound financial management, including reducing FDA Central Account costs (in areas such as telecommunications and postage) by five percent; (2) re-designing management processes; (3) expanding the use of information technology; (4) increasing opportunities for partnering; (5) implementing parts of the FDA Modernization Act; (6) improving the service we provide our customers; and (7) planning for the Agency's future needs.

OMS was instrumental in guiding management initiatives to support the principles of the National Performance Review (NPR), the Government Performance and Results Act (GPRA), and the FDAMA. Some of OMS' major accomplishments in FY 1998 are as follows:

•• Promoted Sound Financial Management ••

FDA CENTRAL ACCOUNT. Reduced FDA Central Account costs (in areas such as telecommunications and postage) by five percent which resulted in a savings of $2.5 million.

PDUFA II FIVE-YEAR PLAN. Led Agency efforts to plan and manage PDUFA funding in accordance with the reauthorization of PDUFA II at the beginning of FY 1998. To ensure that FDA complied with both the FDAMA and the performance goals established for PDUFA II, OMS led a collaborative effort with CBER, CDER, and ORA which resulted in the development of FDA's Five-Year PDUFA II Plan. PDUFA funds benefit the Agency by providing additional resources through industry fees to enhance drug programs and meet program performance goals. The plan was made publicly available and widely accessed through the Internet.

FINANCIAL OPERATING PLAN. Developed and facilitated the first comprehensive Agency Financial Operating Plan in response to direction from the House and Senate Appropriations Subcommittees. Based on the discussions with Subcommittee staff and DHHS, several options were developed for Agency review and discussion, and the final plan was the result of a concerted Agencywide effort.

FY 1999 GPRA PLAN. Developed and submitted the Agency's FY 1999 GPRA Performance Plan to Congress. This is the first time the Agency's performance goals were linked to both its strategic direction and its budget structure. This successful effort was the result of an unprecedented degree of close cooperation and coordination between the planning and budget units of the Agency. The General Accounting Office recognized FDA's plan for its high level of coordination with other DHHS agencies to achieve related goals.

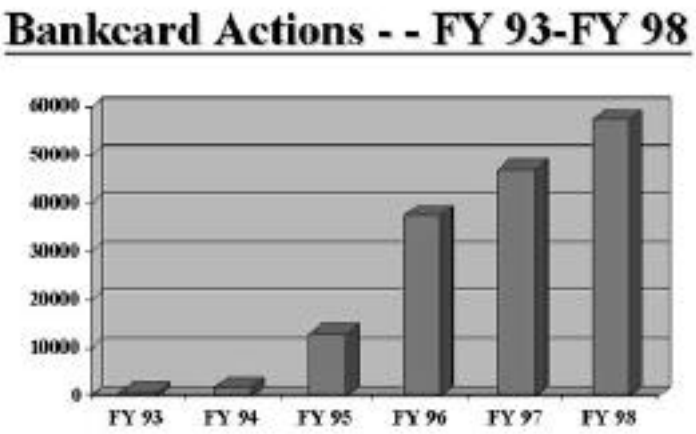
FY 2000 GPRA PLAN GUIDANCE. Developed guidance for FDA Centers and other components for preparation of the Agency's FY 2000 GPRA Performance Plan. This plan builds on the FY 1999 Performance Plan and is designed to reflect the results of planning priority activities for FY 2000 and the Agency's plans for fulfilling the requirements of the FDAMA.

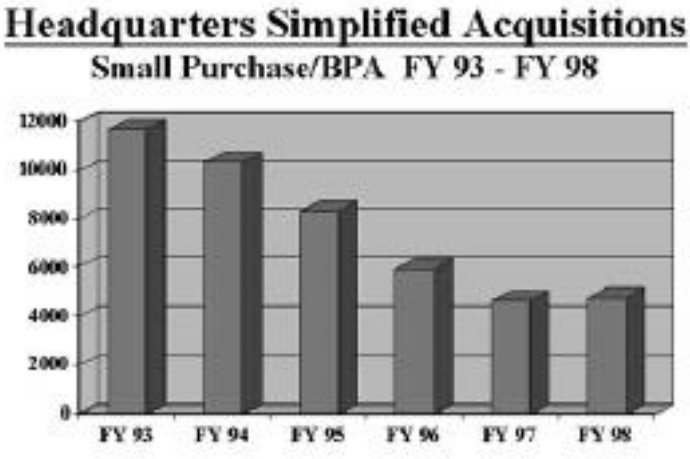
HYPERION ROLL-OUT. Worked with our Center and Office partners to roll out the first Hyperion Enterprise application. Hyperion Enterprise is an off-the-shelf financial consolidation software package that will be used to establish a standardized Agencywide financial system. It provides Web delivery of the FTE reports including total bodies on-board, current FTE on-board, work years used during a current pay period, cumulative work years used to-date, ceiling, and calculated projections. Additional applications will continue to be developed and released.

PAYROLL MANAGEMENT. Facilitated implementation of new payroll management strategies which made Centers and Offices responsible for managing within a payroll budget rather than solely FTE management of prior years. This provides incentives for managers to be aware of and control payroll costs. It also focuses management attention on the cost of personnel decisions and the true cost of specific program functions. To support payroll management, payroll projection models were developed and provided to each component on a bi-weekly basis. These products include a tracking system for all payroll resources and year-end projections based on actual costs as they are incurred.

FREQUENT FLYER MANAGEMENT PROGRAM. Established a team to implement a Frequent Flyer Management Program to manage frequent flyer mileage benefits earned by travelers on official government business. Based on an evaluation done by TravelWare, a frequent flyer management company, there is a potential for nearly $200,000 in Agencywide savings during FY 1999.

BANKCARD PROGRAM. Continued to promote the Bankcard program throughout the Agency. By utilizing this program as opposed to the small purchase and/or blanket purchase agreement mechanisms, the Agency realized an administrative savings of $ 4,772,523 during FY 1998. The following charts show the number of purchase orders compared to the number of Bank Card actions awarded between FYs 1993 and 1998.



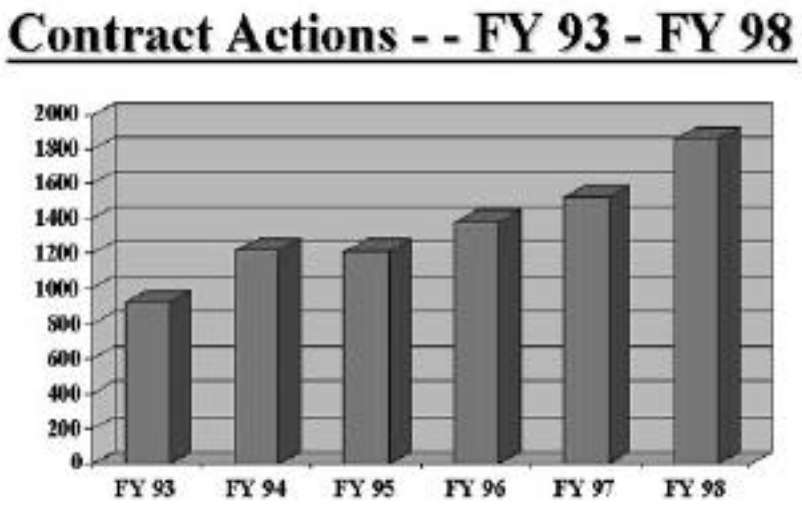


•• Re-Designed Management Processes ••

STRATEGIC ASSET MANAGEMENT PLAN. Continued to develop a strategic asset management plan. This year's efforts were focused on updating the 1997 Laboratory Assessment Report and adding an assessment of all office and laboratory space in the Washington Metropolitan area. Upon completion, this plan will help further the Agency's continued effort to reduce space usage and save costs by providing a comprehensive reference for making facility acquisition, consolidation, and disposal decisions.

REQUISITION CLEARANCE PROCESS. Implemented a simplified requisition clearance process based on recommendations received from the Centers and from non-Center Headquarters components. This will expedite the processing of most agency contracts. The following chart shows the steady increase in the number of contract actions being

processed between FY 1993 - FY 1998:



PROPERTY MANAGEMENT. Worked with all FDA Centers and Offices to implement a comprehensive plan of action to correct noted deficiencies in the Agency's property management and accounting systems. For two years (FY 1996 and FY 1997), the Chief Financial Officers (CFO) audit identified the FDA property system as a material weakness within the Agency. FY 1998 efforts included:

- completion of a wall-to-wall inventory of accountable property
- an intensive (100%) audit of all capitalized equipment
- several random sampling audits of accountable property
- implementation of a more effective property management database system (on an interim basis) and selection of a Commercial Off-The-Shelf (COTS) replacement system
- entry and verification of data into the interim database for all property revision of property management systems and procedures
- implementation of revised procedures for reconciliation of the general ledger and the property management information system

Current reports from the CFO auditors indicate that this year there will not be a material weakness in property management. This progress in our ability to manage property is a testament to the cooperation of the Centers and the Non- Center Headquarters staffs and their willingness to put forth the effort and attention needed to bring the property management system up to par.

HUMAN RESOURCES BENCHMARKING. Participated in a Human Resources (HR) benchmarking study being conducted by the National Academy of Public Administration. This study involved examining personnel processes and defining the new role of HR and options for redirecting resources and reducing costs. When completed, the benchmarking study should facilitate improvements necessary for FDA to achieve enhanced quality HR performance at reduced costs.

PROCESS EXPERTISE TEAM. Collaborated with Agency components to build an internal team capable of providing process expertise to groups engaged in redesigning FDA's core business processes, enabling project teams to reach early consensus on re-design issues and craft consensus action plans for implementation of complex efforts. Supported implementation of key program reinventions within individual Agency components including:

- Center for Devices and Radiological Health re-engineering efforts, including Medical Device Review and regulations development
- Center for Drug Evaluation and Research (CDER) transformation efforts, including the CDER Stretch Planning Group and several Good Review Practices "experiments" to make new drug and biologics reviews more transparent and collaborative
- Office of Chief Counsel redesign efforts, including priority-setting, resource management, and collaborative piloting processes
- Center for Biologics Evaluation and Research Managed Review Process, including Biologics License Application review process mapping and project management

COLLEGE PARK INITIATIVE. Provided leadership and support to a workgroup which developed a comprehensive plan to meet state-of-the-art scientific information needs of those moving to a new FDA facility being constructed in College Park, Maryland. Participants included the Center for Veterinary Medicine (CVM), the Center for Food Safety and Applied Nutrition (CFSAN), and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). JIFSAN (an FDA/University of Maryland partnership) brings

new information partnership opportunities to the Agency.

PROJECT MANAGEMENT. Continued to lead the Agency in developing a state-of-the-art Project Management capability. This included:

- Collaborating with our industry counterparts to maximize the potential synergy between industry and Agency project managers
- Expanding and promoting the use of project management at FDA
- Advocating a new vision for Project Management to evolve the state-of-the-art from Project Management to Decision Management by focusing on science-based decision-making, continuous structured interactions with sponsors to resolve issues, and more process transparency to stakeholders

SES APPRAISAL SYSTEM. Developed a new performance appraisal program for SES executives as an alternative to the required Departmental system. This new program, which closely mirrors the Performance Management Program (PMP) for regular GS employees (developed in FY 1997), involved setting up focus groups and obtaining a great amount of input from managers and employees. SES members were given the opportunity to serve on a task force to review and comment on a draft proposal, and to make suggestions for improving the appraisal process for SES executives. Based on those recommendations, the final appraisal program was approved by the Commissioner and implemented for the FY 1998 review cycle.

•• Expanded Use of Information Technology ••

ENTERPRISE ADMINISTRATIVE SUPPORT ENVIRONMENT. Received DHHS certification to use the EASE system to transmit "live" time and attendance data to DHHS payroll. Our goal is to roll out this system to the entire Agency in July 1999.

INFORMATION TECHNOLOGY INVESTMENT PORTFOLIO. Developed the Agency's first comprehensive IT investment portfolio, expanding on previous efforts to encompass nearly 100 percent of all major IT capital investments and to address the significant funding requirements for annual operations and maintenance activities. The Agency's first Technical Review Board (comprised of Center IRM Directors), was also established to assure that IT initiatives are "credentialed" as "technically sound" in support of the larger IT decision-making process. Total IT costs for FY 1998 and projected costs for FY

1999 and FY 2000 are shown below:

TOTAL IRM COSTS FOR FY 1998 AND PROJECTED COSTS FOR FY 1999 AND FY 2000
($ in 000's)

IT AREA	STAGE	FY 1998	FY 1999	FY 2000	TOTAL
IT Systems By Mission Area	Development/Modernization/Enhancement	38,892	39,243	57,062	135,197
	Steady State	62,382	68,487	66,778	197,648
	Subtotal	101,274	107,730	123,840	332,844
IT Infrastructure and Office Automation	Development/Modernization/Enhancement	--	--	2,000	2,000
	Steady State	17,605	18,014	18,523	54,141
	Subtotal	17,605	18,014	20,523	56,141
IT Architecture and Planning	Development/Modernization/Enhancement	6,461	10,269	5,875	22,605
	Steady State	150	1,600	1,400	3,150
	Subtotal	6,611	11,869	7,275	25,755
Summary	Development/Modernization/Enhancement	45,353	49,512	64,937	159,802
	Steady State	80,137	88,101	86,701	254,939
	Subtotal	125,490	137,613	151,638	414,741

PDUFA II INFORMATION MANAGEMENT PLAN. Utilized the Agency's IT Business Planning Process to develop the Agency PDUFA II Information Management Plan. This plan describes the strategy for budgeting, executing, and managing PDUFA II IT funds during the period FY 1998 to FY 2002, and describes the PDUFA II Electronic Regulatory and Submission Review Program. To foster our continuing partnership effort, this plan has been shared with industry and has been updated to reflect mutual benefits for industry and the Agency.

INFORMATION TECHNOLOGY TRAINING. Established a contractual agreement with Booz-Allen & Hamilton whereby FDA will have unlimited access to their Parklawn Drive training facility for the life of the Strategic Information Systems Technical Integration Resources (SISTIR) contract. This agreement allowed the Agency to avoid the cost of $466,000 to build a lab and training facility.

TELECOMMUNICATIONS ASSESSMENT. Performed a complete assessment of the telecommunications operation and budget to more effectively manage the telecommunications operations and to reduce waste and redundancy. As a result, a one time savings/cost avoidance of $192,000 was achieved and a recurring savings/cost avoidance, beginning in FY 1998, of $276,000 was also achieved, resulting in an overall savings/cost avoidance of $468,000 for FY 1998.

FY 1998 SAVINGS/COST AVOIDANCE REALIZED FROM I.T. INITIATIVES

AREA OF SAVINGS/COSTS AVOIDANCE	FY 98 SAVINGS
Misuse of Government telephone lines by an FDA contractor (Agency received a $37K Credit)	$37,000
Erroneous charges on 397 telephone lines	$80,000
International calls	$18,000
Unused circuit costs	$75,000
Telecommunications Improvement Project Acount	$258,000
Total Savings	$468,000

INFORMATION SYSTEMS ARCHITECTURE. Initiated Agencywide implementation of the ISA project. Pilot year implementation began in June 1998, and by year's end one-third of the Agency will be completed, with plans for full implementation by FY 2000 (depending on fund availability). This year's accomplishments eliminate barriers in exchanging regulatory documents between Center regulatory writers and the Office of Commissioner policy resources, and facilitate seamless exchange of information between organization components in which ISA has been implemented.

EXPANDED INTERNET CAPABILITY. Implemented and significantly expanded the Agency's Internet capability, which had reached capacity and experienced significant failures during FY 1997. This included re-hosting the Agency's Internet site as well as migrating information from existing center Internet sites, redesigning home pages, and optimizing effectual linkages of information. Our Internet site has been cited by key users and stakeholders as being "best of breed" worldwide.

INFORMATION TECHNOLOGY POLICIES. Developed comprehensive IT policies that reflect the changes resulting from the Clinger-Cohen Act and the repeal of the Brooks Act, necessitating the need for the Agency to better manage its IT resources. Emphasis will now be on the development of critical new policies to assure the Agency is well-positioned to meet the challenges of future years. A new policy developed this past year was an IT acquisition policy as well as a new IT security policy to address the "scrubbing" of electronic storage media. The latter policy clearly outlines roles and responsibilities, establishes standard certification language on inventory forms, identifies tools for "scrubbing" each type of computer storage device, and defines procedures to assure a clear audit trail and accountability.

YEAR 2000 COMPLIANCE. Provided leadership and focus for the Agency's Year 2000 compliance mandates. The Agency was consistently ahead in achieving OMB and Departmental mandated objectives and reporting requirements. Through judicious management and proactive and effective operational controls, we have prevented the Agency from experiencing penetrating oversight investigations. Additionally, the program has been conducted at a minimal expense to the Agency and structured to minimize the impact on in-house resources.

•• Increased Opportunities For Partnering ••

PARTNERING OPPORTUNITIES WEB PAGE. Established an "FDA Partnering Opportunities" web page. The web page advertises opportunities for interested parties to form public-private partnerships with FDA Centers. Partnerships will be formalized through Cooperative Research and Development Agreements, contractual arrangements, or innovative partnerships.

WORKFORCE DIVERSITY. Continued to focus on increasing the diversity of the Agency workforce by establishing and maintaining effective working relationships with various minority organizations and recruitment sources including:

- The Hispanic Association of Colleges and Universities' National Internship Program
- The President's Welfare to Work Initiative
- The Interamerican College of Physicians and Surgeons Intern Program
- The National Association for Equal Opportunity in Higher Education, including

Historically Black Colleges and Universities

EDUCATION/OUTREACH. Developed an education/outreach program to inform Agency managers of successful asset leveraging efforts and identifying new ways or mechanisms to leverage assets or defer costs.

•• Implemented Sections of the FDA Modernization Act ••

FDA MODERNIZATION ACT ACTIVITIES. Embraced the FDAMA, which presented the Agency with many new obligations over and above its already full agenda associated with statutory requirements. Major activities included:

- Developing initial cost estimates for FDAMA implementation, focusing on requirements with significant dollar and/or FTE costs, including 15 requirements with costs of $1 million or more and 48 with costs of more than $100,000.

- Establishing a project management system for FDAMA implementation, which involved over 365 actions steps required to implement 86 tasks, each led by a multi-organizational team. Worked collaboratively with Center and Office project leaders to negotiate time lines consistent with statutory deadlines, providing standard and customized reports to record and track these. Coordinated broad involvement in cross-cutting projects, and facilitated resolution of issues that arose. Kept Agency management advised on implementation progress.

- Accepting comments on FDA's regulatory documents electronically. With the publication of the first FDAMA docket in July 1998, FDA invited the public to provide comments by e-mail and on the FDA web-site. Electronic comments save time, postage, and paper for both the public and for Agency personnel.

- Researching the current FDAMA section 407 submission tracking environment and developing a report to consolidate information gathered and submissions falling within the scope of this report to Congress.

- Supporting rulemaking activities for six Centers through the development of 118 Paperwork Reduction Act information collection (IC) packages and processing of 28 ICs to assure implementation within statutory deadlines. Addressed the Agency backlog of existing ICs.

- Implementing a training and awareness program for new regulations staff devoted to FDAMA rules. Developed a streamlined approval process with

policy and legal staff to facilitate timely FDAMA program implementation.

- Conducting eight Stakeholder Engagement Forums in accordance with FDAMA, Section 406(b), in order to hear from our stakeholders on how FDA might best meet the requirements of the FDA Modernization Act. The success of these meetings was the result of Agencywide efforts and the commitment of the entire FDA management team.

•• Improved Customer Service ••

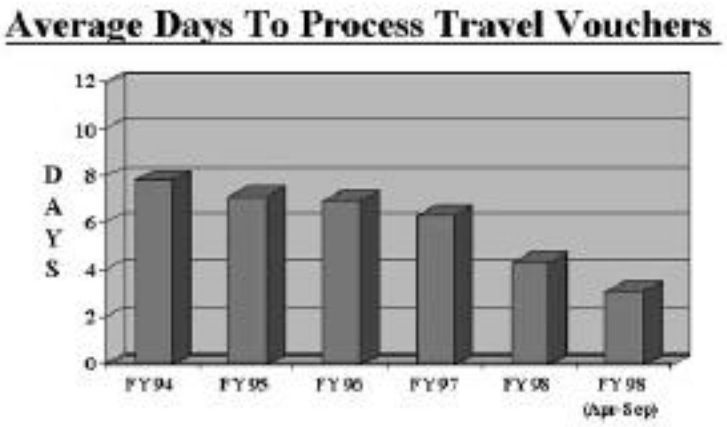
ENHANCED ELECTRONIC COMMUNICATION. Expanded Intranet and Internet services by adding new web sites, expanding coverage, upgrading systems, and providing increased opportunities for electronic communication between OMS and others. Some of OMS' most significant FY 1998 Intranet/Internet improvements included:

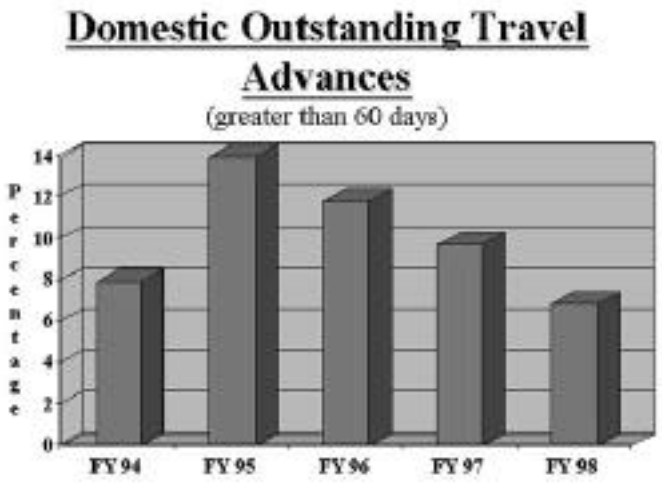
- expanding FDA's Internet capability by moving the main server to UUNET, a Web-hosting company. This provided additional storage for data, increased bandwidth, faster performance, higher security, and more reliable service.
- posting FDA's FY 1999 Performance Plan on the Internet
- providing Intranet web delivery of FTE financial reports via Hyperion Enterprise software
- making all external FDA vacancy announcements available on the OPM Internet site (www.usajobs.opm.gov)
- providing FDA Intranet users access to secured interactive financial management applications including the travel payment query system, cash awards, overtime and FTE systems, payroll error notice tracking system, travel payment system, and the payroll data query system
- expanding FDA's Dockets Internet web site to include FDA's Federal Register documents, FDAMA documents, and 1997/1998 Advisory Committee transcripts
- establishing an "FDA Partnering Opportunities" Internet site to advertise opportunities to form public-private partnerships with FDA Centers
- adding information regarding technology transfer to the Intranet

BUDGETING CONCEPT. Implemented a new budgeting concept which allows each

Center to review operating and payroll costs as a total, and make decisions concerning the proper mix of payroll and non-payroll resources. Under this new concept, accountability for the cost of personnel decisions is assigned to the organizational level which actually makes those decisions.

TRAVEL VOUCHER PROCESSING TIME. Reduced the number of business days it takes to reimburse a traveler for travel related expenses from 5-8 business days to 2-3 business days by converting to Electronic Funds Transfer and continued to reduce the number of domestic outstanding travel advances. Saved approximately $30,000 annually in Headquarters by eliminating the processing of Third Party Drafts through Riggs National Bank. The following charts depict the reductions in travel voucher processing time and the percentage of outstanding travel advances:





FACILITIES PARTNERING AGREEMENTS. Discontinued the establishment of a Facilities Help Desk due to implementation of Partnering Agreements with Center components. These agreements allow the Centers to handle their own day-to-day facilities complaints,

and seek our assistance only on major issues. Our experience with the newly implemented Partnering Agreements has shown that a Facilities Help Desk was not necessary.

HUMAN RESOURCES COUNCIL. Established a Human Resources Council, composed of senior staff from the management offices of each Center/Office and human resources personnel. The council meets monthly, and offers a forum for providing information on HR issues, hearing what the HR issues are in the centers, and sharing best practices.

QUALITY OF WORK LIFE. Completed a variety of successful Quality of Work Life (QWL) initiatives including:

- made plans for the celebration of the second annual QWL week. The DHHS Secretary, Donna Shalala, continued to emphasize the importance of allowing employees to balance their work and family life to be more satisfied and productive;
- participated with the Deputy Secretary, Kevin Thurm, Chair of the Labor-Union Partnership Council, in the oversight of the Quality of Work Life initiative and planned for a two day conference at the Department to highlight the accomplishments and explore new opportunities;
- developed a partnering model for new policies and initiatives which recognizes bargaining unit's and management's joint concern for improvement in the overall quality of work life for all FDA employees;
- developed a mentoring workshop as part of FDA's Leadership Development Program so future Agency leaders will have strong mentoring skills;
- developed an FDA Change Management Model as guidance for organizations undergoing change and transition;
- identified specific areas for improvement in the categories of communication and management practices;
- designed and introduced an FDA Alumni Program which provides a mechanism for retirees to maintain contact with FDA and allows FDA to have continued access to their many talents and wealth of institutional knowledge;
- provided FERS transfer seminars to ensure that FDA employees had sufficient information to make informed decisions about transferring from the Civil Service Retirement System to the Federal Employees Retirement System;
- conducted empolyee interviews to gather input concerning ways to improve and reengineer the FDA Suggestion Program.

ELECTRONIC DOCKETS. Provided dockets documents electronically to various customers and saved 155,056 pages of paper and $15,050 in duplicating costs. In the case of FDA's most popular docket, the customer would have paid $9,146 in duplicating costs for a paper copy, but instead paid only $232 for the electronic media. Agency components also benefitted from the electronic documents by receiving critical rulemaking documents via e-mail on a timely basis. During FY 1998, customers downloaded approximately 658,405 files directly from the Dockets Web site, as shown in the following chart:

DOCKETS MATERIALS PROVIDED ELECTRONICALLY VIA INTERNET

MONTH	VIEWS	USER SESSIONS	POINT OF ENTRY USERS	DOWNLOADS
February	N/A	N/A	N/A	12,042
March	5,008	3,764	1,430	3,989
April	8,827	7,190	3,131	9,245
May	8,506	7,012	3,287	46,649
June	9,295	7,572	3,390	83,565
July	9,416	7,605	3,547	209,129
August	8,903	6,911	3,164	156,672
September	8,845	6,681	2,911	137,114
FY 98 TOTAL	**58,800**	**46,735**	**20,860**	**658,405**

Note: These figures represent only 8 months of operation. Dockets website data first became available for downloading in February 1998.

•• Planned for Future Needs ••

STRATEGIC MANAGEMENT FORUM. Instituted a semi-annual Strategic Management Forum of senior Agency managers. The first of this series was in October 1997 where senior managers identified priority areas. They concluded that the most critical driver for FDA strategic and budgetary decisions is its international objectives, including setting

standards, providing technical assistance, and regulating imports. In November 1997, they held a follow-up meeting with international experts to determine how the Agency should position itself in the international arena to serve the public health interest of the American people. The outcome was a decision to develop an FDA international strategic plan.

STAKEHOLDER ENGAGEMENT FORUM - 406(b) FDAMA. Planned and developed the June 1998 FDA Stakeholder Engagement Forum. This forum resulted in an Agency strategy for systematically consulting with our stakeholders for their input on modernizing FDA over the next several years as required in Section 406(b) of the FDAMA. A series of eight meetings were held with stakeholder groups from each of the areas regulated by the FDA. Participants included scientific and academic experts, health care professionals, patient and consumer advocacy groups, and regulated industry. They provided a wide range of recommendations about FDA's future directions and strategies which are being incorporated into the Agency's strategic and operational plan for FY 1999 and beyond and are required as part of the development of the 406(b) plan under FDAMA.

INFORMATION SYSTEM - 407 FDAMA. FDAMA's Section 407, titled "Information System" mandates that FDA will establish and maintain an information system to track the status and progress of each application or submission requesting Agency action. The legislation also requires the Agency to report by November 21, 1998 on the status and projected costs associated with this tracking system and concerns about confidentiality. The Agency researched the current submission tracking environment and developed a report consolidating information gathered and enumerating submissions falling within the scope of this report to Congress. The report documents whether the status and progress of each submission is tracked in an existing information system, and describes the high-level characteristics of each system. Finally, the report documents FDA's approach to establishing an information system as referenced in FDAMA section 407, its status, and the proposed activities and associated costs over the next four years.

STRATEGIC RESOURCE GAP ANALYSIS. Facilitated an Agencywide effort to identify and evaluate program requirements and shortfalls, or gaps in Agency resources. In the context of a strategic action plan, a consensus was achieved concerning the Agency's priorities for FY 2000 and beyond. This formed the basis for the program resource requests submitted in the FDA FY 2000 budget request. The FY 2000 request will also be integrated into the Agency's performance plan and goals, and will serve as the basis for the FDAMA Report.

FACILITIES PLANNING AND CONSTRUCTION. White Oak Consolidation: The consolidation of FDA was authorized through the FDA Revitalization Act of 1990. Funding was provided through multiple appropriations occurring from 1992 through 1995. In 1995, funding was rescinded for the consolidation that was to occur in Montgomery County, Maryland at the Clarksburg site. Since the rescission, the Naval Surface Warfare Center, a 700-acre site in White Oak, Maryland, was transferred to the General Services Administration (GSA) through the Base Realignment and Closure Act process. GSA has proposed a consolidation project for FDA at this site. The consolidation will replace all the existing fragmented facilities which support the Office of the Commissioner, the Office of Regulatory Affairs, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research. The development will consist of new laboratories, office buildings, and support facilities.

SPACE REQUIREMENTS

(In Occupiable Square Feet) - Personnel = 5,947 Occupants

Office	913,977
Laboratory and Animal Holding	250,333
Shared Use	278,850
Central Plant and Building Links	54,400
Total Occupiable Square Feet	1,497,560

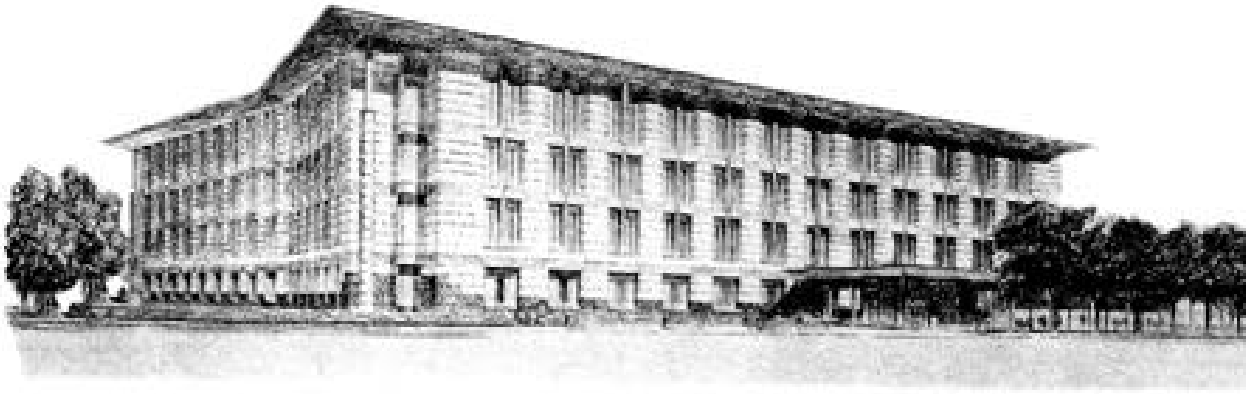
Since capital funds have not been forthcoming for this project, GSA and FDA have proposed a Public/Private Partnership as an alternative means of financing FDA's consolidation at White Oak. The private partner, LaSalle Partners/Moore and Associates in concert with GSA and FDA, have developed a Business Plan which proposes a combination of traditional leases for office space and direct capital construction of the laboratories. The Business Plan proposes development of the entire White Oak site and provides opportunities for other government agencies and commercial interests. Authorization of the Businesses Plan will require Office of Management and Budget (OMB) and Congressional Approval.

Working closely with GSA, we have helped develop a financial strategy which we hope will satisfy OMB and Congress. The financial strategy proposes leasing or selling land

to the private sector for the purpose of developing office buildings that would be leased to meet the FDA requirement. The revenue from the land lease or sale would be used to partially fund the construction of FDA's requirement for special use laboratories. These laboratories are to be government owned. The financial strategy would significantly reduce public sector funding of the approximately $500 million construction project. Additional authorities needed by GSA to execute the financial strategy are:

- authority to utilize ground lease revenue for capital construction
- authority to convey property through sale or ground lease
- authority to implement development without full and open competition

College Park Building: Continued to work toward completing the construction of the FDA College Park Building. This building, costing approximately $62 million, will consist of approximately 430,000 gross square feet of space and will house the consolidated offices and activities of CFSAN and state-of-the-art laboratories for CFSAN and JIFSAN researchers, as well as several teaching laboratories. CVM occupancy of the building has been reduced to a contingent that will be part of the JIFSAN collaborative research. The GSA completion date for the project is March/April, 2001.



Design Completed FY 1998

Arkansas Regional Laboratory: Continued with the construction of the approximately $32 million multi-purpose Arkansas Regional Laboratory (ARL) building in Jefferson, Arkansas. The facility, which will consist of approximately 145,000 gross square feet of space, will assume many of the laboratory/analytical functions performed by the Chicago District laboratory and will also assume the analytical and laboratory functions

and personnel from the Dallas, Minneapolis, and Detroit laboratories when those facilities close, except for Detroit's human drug functions and CDRH program work from Minneapolis. Phases I and II of the three phase project, construction of laboratories, is scheduled for completion in December, 1999. Only partial funding has been appropriated for Phase III of the project, construction of administrative offices.

New York (Jamaica, Queens) Laboratory: Continued with the construction of the multi-purpose New York laboratory and office facility to replace existing, outmoded space for the Northeast Region, District, and Regional Laboratory. The new building, which will be complete by mid December, 1999, is being constructed at a cost to the developer and owner (Hines Co.) of about $70 million. The building is comprised of approximately 275,000 gross square feet.

Cincinnati Laboratory: Continued working toward the completion of the National Forensic Chemistry Center project in Cincinnati, Ohio. This facility was occupied by the District Office and the Forensic Chemistry Center on July 17, 1998 and was officially dedicated on October 6, 1998. The building, which won a design award, is comprised of approximately 75,000 gross square feet and was constructed on an 8.35-acre developer-owned site. Procurement of the facility was through a lease arrangement with GSA. The lease costs to GSA will be approximately $2.24 million per year. The Forensic Chemistry Center is designated as a specialty lab under the FDA Field Laboratory Restructuring in the Office of Regulatory Affairs Century 21 Plan.

Los Angeles (Irvine) Laboratory: Continued working towards the acquisition of approximately $40.4 million in Congressional appropriations for construction and management costs of the multi-purpose Los Angeles (Irvine) Laboratory which will allow for relocation of the laboratory functions from the West Pico Boulevard facility, as well as permitting the assumption of Seattle's current drug functions. The new facility will provide approximately 130,000 gross square feet of laboratory and office space. Design of the new building is 95% complete. A ten-acre site adjacent to the University of California at Irvine was acquired in 1997.

LEARNING ORGANIZATION OPPORTUNITIES. Expanded learning opportunities for employees that enhance not only current skills, but also enable mastery of new skills and technologies necessary to meet the demands of a highly scientific/regulatory Agency such as FDA.

- Sponsored an Agencywide Training Officers Retreat to establish communication and networks so that training and developmental opportunities available in one organization can be shared with others throughout the Agency.

- Developed a mentoring model to provide FDA organizations with a framework for low or no cost developmental opportunities for employee learning and development.

- Developed a special briefing for senior managers which outlines the next steps the Agency could take to more effectively become a learning organization. This is a follow-up to the briefing presented at the strategic management forum.

STRATEGIC WORKFORCE PLANNING INITIATIVE. Began an Agency Strategic Workforce Planning Initiative to identify future workforce needs and develop a roadmap to address these needs by: (1) identifying the priorities and changing role of FDA (incorporating the results of the Agencywide Gap Analysis), (2) identifying the resources, particularly the human resources, necessary to address the priorities and "gaps" and (3) developing strategies to take us from where we are now to where we need to be, including:

- augmenting recruitment sources to ensure the best possible candidate pool for future positions

- enhancing our broad-ranging learning and development strategies to ensure we are maintaining and/or enhancing the necessary skills, knowledge and abilities of our employees from entrance on duty to retirement

- reinforcing the "dual track" of advancement within FDA so that advancement does not depend solely on becoming a supervisor

- developing a competency-based, leadership-specific succession model and certification program to prepare our leaders for the task of leading in the 21st century

CANDIDATE EVALUATION SYSTEM. Reinvented the candidate evaluation system for the Consumer Safety Officer career field, one of FDA's largest occupations. State-of-the-art methodology is being used in the study, as well as the services of University of Maryland statisticians for validation. The new candidate evaluation system includes a structured interview as part of the screening and scoring process. During the hiring effort for the Food Safety Initiative in the Office of Regulatory Affairs, 483 applicants participated in the structured interview process for referral to about 60 positions nationwide. The applicants that are hired will be tracked to measure the success of the new evaluation and selection process.

Major Challenges for the Future

The OMS team is proud of FDA's FY 1998 managerial accomplishments and looks forward to the challenges ahead. In FY 1999, OMS will continue to work with all organizational components of the FDA management team to position the Agency, within the constraints of its very tight budget, to meet the 21st century with near state-of-the-art technology, re-designed cost management systems, streamlined business processes, and innovative approaches to meeting our customer needs with fewer resources. A discussion of some of the high priorities on which OMS plans to focus in FY 1999 follows.

•• People ••

Partner with NTEU to provide for successful partnering and pre-decisional interaction with the Union. Partnership activities will include:

- training supervisors, managers, and union representatives about collective bargaining;
- negotiating an agreement with the Federal Labor Relations Authority to provide managers, supervisors, and union officials training in partnership principles, interest-based negotiations, and alternative dispute resolution;
- negotiating a collective bargaining agreement and, upon completion, providing training throughout the FDA;
- establishing consensual methods of dispute resolution, particularly mediation, to address and resolve workplace issues;
- establishing and maintaining a proactive, collaborative, and pre-decisional relationship;
- establishing FDA/NTEU Partnership Councils at the appropriate FDA-wide and Center/District/Region levels

Institutionalize the Strategic Workforce Planning Initiative by:

- identifying the various skills mix and competencies needed in the workforce of the future;
- identifying gaps in current and future human resources needs;
- developing strategies to address resource needs and providing a roadmap to

help us get where we need to be

Reduce Agencywide costs of the Workers' Compensation Program by five percent through aggressive management of new cases, review of long-term cases for return-to-work possibilities, and pursuit of the decentralization of program costs to Offices/Centers/Districts. Part of this effort will involve providing training to supervisors and revising the Department of Labor's report of medical and compensation costs charged back to the FDA.

Continue efforts to improve the Quality of Work Life for FDA employees including:

- providing an annual benefits statement to all employees
- offering a seminar series on improving communication
- providing a simple, flexible, and as paperless as possible mechanism to recognize employees for suggestions that improve the quality of work life in both their immediate organization and throughout FDA (i.e., institutionalize the new FDA Suggestion Program

•• Money ••

Fully implement more cost effective payroll management throughout the Agency. In support of this change, additional detailed payroll tools and data will be made available electronically to assist operating components in managing payroll.

Expand financial software capabilities enhancing financial management processes including the full implementation of Hyperion budget execution applications. This includes:

- The ability to access spending data across various time periods and to vary the content and level of detail according to Center and/or Office needs.
- The issuance of allotments/allowances, transfers, budget histories and financial operating plans electronically.
- The full implementation of the Hyperion Budget Execution System to all Centers during FY 1999.

Continue to strengthen FDA's financial systems capabilities by:

- enhancing the timeliness and availability of financial information to our

customers through expanded electronic access to data and reports, and the expanded use of the Office of Financial Management Web site to share information and communicate changes in financial procedures and policy more effectively.

- continuing to improve the quality, timeliness, and usefulness of financial and program information in FDA's financial statements, in collaboration with our DHHS and FDA partners, toward achieving an unqualified FY 1999 audit opinion.
- fully implementing expanded Electronic Funds Transfer capabilities Agencywide for all kinds of payments enhancing customer service to FDA employees and external business partners.

•• Things ••

Use innovative financing and contractual mechanisms to upgrade infrastructure in both Headquarters and field offices in accordance with the Energy Policy Act (P.L. 102-486) and Executive Order 12902. These activities will enable the Agency to receive new, more efficient equipment without having to provide up-front federal funding.
Continue efforts to implement a property management system that will meet the needs of the Agency and that can easily interface with the Acquisition and Financial systems as appropriate.

Continue to explore and develop mechanisms for leveraging FDA assets such as enhancing the education/outreach program and identifying new ways or mechanisms to leverage assets or defer costs.

Continue to work with GSA and OMB to consolidate FDA at the White Oak, Maryland site through a combination of public and private sector investments and continue facilities planning and construction efforts for the College Park, Maryland building and for FDA laboratory consolidation in New York, Arkansas, and Los Angeles (Irvine).

Establish an Agency-wide workgroup to examine issues related to current space usage. One of the main goals of this workgroup will be to identify and recommend incentives that would prompt more efficient space utilization.

•• Plans and Evaluations ••

Assure the implementation of performance-based planning, management, and budget systems.
Continue to develop and implement an Agencywide platform for strategic and budgetary decision making through the use of systematic processes for developing consensus/priorities among FDA senior managers.

Ensure that FDAMA planning and reporting requirements are met in a timely and complete manner.

•• Systems ••

Deploy and fully implement the ISA by FY 2000 while supporting the legacy infrastructure to assure interoperability of FDA systems and guide future IT investments.

Ensure that all FDA mission critical systems are verified Y2K compliant by December 31, 1998 and other systems are compliant by March 31, 1999.

Implement the EASE Time and Attendance module Agencywide by September 30, 1999.

•• Strategic Management ••

Continue the semiannual Strategic Management Forum that brings together senior Agency managers to discuss high priority management activities and focus the skills and talents of these people on providing the strategic direction for the Agency.

Continue to consult with Agency stakeholders to update Agency plans required under section 406(b) of FDAMA.

Revise Agency strategic directions to reflect current stakeholder and Agency management thinking.

For More Information

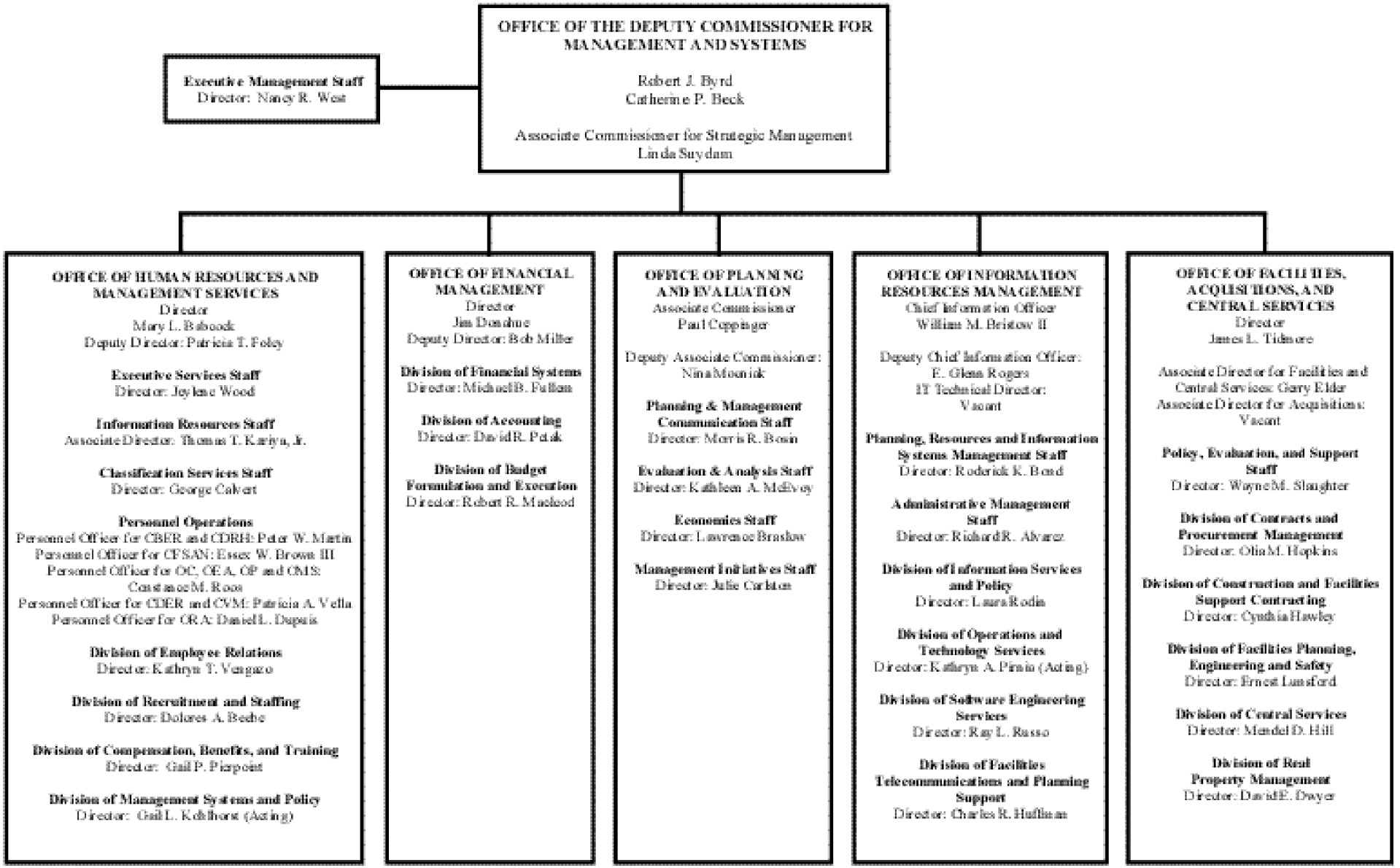
The OMS team is pleased to work with all FDA personnel as we strive to protect, promote, and enhance the health of the American people. For more information about OMS services and systems, please contact:

- Deputy Commissioner for Management and Systems, (301)-827-3443
- Associate Commissioner for Strategic Management, (301)-827-3330
- Director, Office of Human Resources and Management Services, (301)-827-4120
- Director, Office of Financial Management, (301)-827-5001
- Director, Office of Facilities, Acquisitions, and Central Services, (301)-827-6890
- Associate Commissioner for Planning and Evaluation, (301)-827-5292
- Chief Information Officer, (301)-827-4280

Additional information about OMS programs is also available on FDA's Intranet (http://learnfda.fda.gov), and on the Internet (http://www.fda.gov) for information on PDUFA and Dockets Management.

FOOD AND DRUG ADMINISTRATION

OFFICE OF MANAGEMENT AND SYSTEMS



November 18, 1998